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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference YCT-848	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/011642	International filing date (day/month/year) 11 September 2003 (11.09.2003)	Priority date (day/month/year) 11 September 2002 (11.09.2002)
International Patent Classification (IPC) or national classification and IPC C07K 1/14, 16/00		
Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 11 September 2003 (11.09.2003)	Date of completion of this report 10 June 2004 (10.06.2004)
Name and mailing address of the IPEA/JP	Authorized officer

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International Application No.

PCT/JP2003/011642

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☒ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of these sheets may be marked "unrecorded"

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/JP03/11642

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 21-22

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 21-22
are so unclear that no meaningful opinion could be formed (*specify*):

In the Specification only several specific items are described as purified physiologically active proteins obtained by the method that includes the specific purification process described in claims 21 and 22. Therefore, support and full disclosure by the Specification of the inventions of claims 21 and 22 are lacking. Moreover, when the level of technology at the time of filing is considered, it is entirely unclear whether all purified physiologically active proteins are included in the scope of this definition.

Therefore, because a meaningful investigation into the inventions described in the above claims cannot be performed, no opinion can be rendered.

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 21-22

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/JP03/11642

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claim	19	YES
	Claims	1-18, 20	NO
Inventive step (IS)	Claims		YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO

2. Citations and explanations

Document 1: JP 2000-319294 A (Asahi Chemical Industry Co., Ltd.) November 21, 2000
 Document 2: WO 99/19343 A1 (Ortho-Clinical Diagnostic Systems, Inc.) April 22, 1999
 Document 3: EP 1225180 A2 (Probitas Pharma, S.A.) July 24, 2002
 Document 4: JP 2000-351799 A (JPR Pharmaceuticals Co., Ltd.) December 19, 2000
 Document 5: WO 97/3706 A1 (Croix-Rouge de Belgique) February 6, 1997
 Document 6: EP 610729 A1 (Dr. Karl Thomae GmbH) August 17, 1994

•Claims 1-18 and 20

Based on the description in document 1 cited in the international search report, the inventions of claims 1-18 and 20 lack novelty. The Claims and Examples of document 1 disclose a method for removing impurities from samples containing the physiologically active proteins described in claims 1-18 and 20.

It is necessary to note the point that the conductivity, ionic strength, and the conductivity of the aqueous solution specified in the present application cannot be clearly distinguished from those of the aqueous solution described in document 1.

•Claims 1-6, 8, 10-18, and 20

Based on the descriptions in document 2 and 3 cited in the international search report, the inventions of claims 1-6, 8, 10-18 and 20 lack novelty. The Examples and Figures of documents 2 and 3 disclose a method of removing impurities in a sample containing the physiologically active proteins described in claims 1-6, 8, 10-18, and 20.

It is necessary to note the point that the conductivity, ionic strength, and the conductivity of the aqueous solution specified in the present application cannot be clearly distinguished from those of the aqueous solutions described in documents 2 and 3.

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP03/11642

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
EP 1247818 A2 (Ortho-Clinical Diagnostic Systems, Inc.) [P,X]	09.10.2002	02.04.2002	02.04.2001

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V:

•Claims 1-6, 8, 17-18 and 20

Based on the descriptions in documents 4 and 5 cited in the international search report, the inventions of claims 1-6, 8, 17-18 and 20 lack novelty. The Claims, Examples, and Figures of documents 4 and 5 disclose a method of removing impurities in a sample containing the physiologically active proteins described in claims 1-6, 8, 17-18, and 20.

It is necessary to note the point that the conductivity, ionic strength, and the conductivity of the aqueous solution specified in the present application cannot be clearly distinguished from those of the aqueous solutions described in documents 4 and 5.

•Claim 19

Based on the descriptions in documents 1-6 cited in the international search report, the invention of claim 19 lacks an inventive step.

The inventions described in documents 1-6 address the same technical issue of removing impurities from a sample containing a physiologically active protein. Persons skilled in the art can easily conceive of applying the well known protein A or protein G affinity chromatography as described in document 6 to the inventions described in documents 1-5 to solve the common technical issue.

Moreover, this examination finds that so doing does not produce any particularly outstanding effect.